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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,802	10/29/2001	Berthold Kramm	P-8916.00	3132
27581	7590	11/15/2004	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			KENNEDY, SHARON E	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/041,802

Applicant(s)

KRAMM ET AL.

Examiner

Sharon Kennedy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-11, 14 and 15 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19-31 is/are allowed.
- 6) ☒ Claim(s) 12, 13 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 May 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>all</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

Election/Restrictions

Applicant's election with traverse of Species 1, Figures 3 and 4 in the reply filed on July 22, 2004 is acknowledged. The traversal is on the ground(s) that there is no burden to examine all the species since they are closely related. This is not found persuasive because applicant has submitted 7 different species. Clearly there is a burden. If there were only 2 or 3 species, an election might not have been required. In addition, applicant should be grateful that a restriction requirement was not required between the method and apparatus. Accordingly, the examiner is already undertaking additional unnecessary burden to expedite prosecution. Thus, applicant's arguments are unpersuasive. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-11, 14 and 15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected specie, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 22, 2004.

Applicant stated that all of claims 12-22 and 27-31 read on elected specie 1, Figures 3 and 4. This is not accepted because claims 14 and 15 are directed to Figure 7, which has no separate passageway for drug delivery. See [0038] of the published

application, US 2003/0083725, for clarification. Accordingly, claims 14 and 15 are also withdrawn.

As regards claims 23-26, these are rejoined because the method is found to be allowable.

Drawings

Figures 1 and 2 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g).

Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.121(d)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

Claims 12, 13, 16, 17, 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is unclear how the distributor 48

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of Figures 3 and 4 are operable to disperse a vasodilating agent since it doesn't have any orifices. It looks just like a balloon catheter, remarkably like the balloon catheter in US 5,571,161.

Claim Rejections - 35 USC § 102

Claims 12, 13, 16, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Machold et al., US 5,611,775. Although Machold is for an entirely different purpose other than inserting a lead, the structure shown is identical to the claimed structure. The balloon serves as the distribution device and the guide wire lumen serves as the lumen capable of transporting an electrical lead.

Allowable Subject Matter

Claims 19-31 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: The claims recite the method of using a vasodilator to dilate the cardiac vein to enable the insertion of a cardiac lead. The prior art is directed to mechanical means to dilate a vessel to insert a lead. Accordingly, the claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571/272-4955.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink that reads "Sharon Kennedy". The signature is fluid and cursive, with the first name "Sharon" and last name "Kennedy" clearly distinguishable.

Sharon Kennedy
Primary Examiner
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Sek